K081880

## 510(k) SUMMARY

OCT - 2 2008

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| Manufacturer: | Atlas Spine, Inc. |
| Address: | 1555 Jupiter Park Drive, Suite # 4<br>Jupiter, FL 33458 |
| Telephone: | 561-741-1108 |
| Fax: | 561-741-1870 |
| Official Correspondent: | Jeannette G. Dailey |
| Title: | Vice President Regulatory Affairs &<br>Quality Assurance |
| Telephone: | 561-354-4319 |
| Device Classification: | Intervertebral body fusion device<br>Class II per 21 CFR §888.3080<br>Product Code: ODP, MAX<br><br>Spinal intervertebral body fixation orthosis<br>Class II per 21 CFR §888.3060<br>Product Code: MQP |
| Trade/Proprietary Name: | Atlas Spine Spacer |
| Common Names: | Intervertebral Body Fusion Device [IBFD]<br>Vertebral Body Replacement [VBR] |
| Predicate Devices: | Atlas Spine Vertebral Body Replacement<br>Atlas Spine, Inc.<br>K063464<br><br>IMPIX Interbody Device<br>MEDICREA Technologies<br>K072226 |

Intended Use:

Intervertebral Body Fusion Device: The Atlas Spine Spacer is indicated for intervertebral body fusion in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine at one disc level from C3-C7. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. This device is to be used with autogenous bone graft. The Atlas Spine Spacer is to be used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

The Atlas Spine Spacer is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels(s). This device is to be used with autogenous bone graft. The Atlas Spine Spacer is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

Vertebral Body Replacement: When used as a vertebral body replacement, the Atlas Spine Spacer is intended for use in the thoracolumbar spine (T1-L5) for partial or complete replacement (i.e., vertebrectomy) of a diseased vertebral body resected or excised for the treatment of tumors in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Atlas Spine Spacer is also indicated for treating fractures of the thoracic and lumbar spine.

The Atlas Spine Spacer is designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column, even in the absence of fusion for a prolonged period of time. The interior of the Atlas Spine Spacer can be packed with bone. This device is intended to be used with supplemental spinal fixation systems that have been cleared for use in the thoracic and/or lumbar spine (i.e., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems).

Device Description:

The Atlas Spine Spacer is a rectangular, radiolucent device in various sizes. The device design includes four radiopaque markers, two on the superior surface and two on the inferior surface, in opposing corners, that allow postoperative radiographic confirmation of the device position and orientation.

Equivalence to Marketed Product

The Atlas Spine Spacer was shown to be substantially equivalent to previously cleared devices and has the same indications for use, design, function and material.

Performance Data

Pre-clinical data per ASTM F2077 have been submitted to characterize the Atlas Spine Spacer.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 2 2008

Atlas Spine, Inc.
% Ms. Jeannette G. Dailey
Vice President Regulatory Affairs & Quality Assurance
1555 Jupiter Park Drive, Suite #4
Jupiter, FL 33458

Re: K081880
Trade/Device Name: Atlas Spine Spacer
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: July 1, 2008
Received: July 8, 2008

Dear Ms. Dailey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K081880

Device Name: Atlas Spine Spacer

Indications for Use:

Intervertebral Body Fusion Device: The Atlas Spine Spacer is indicated for intervertebral body fusion in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine at one disc level from C3-C7. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. This device is to be used with autogenous bone graft. The Atlas Spine Spacer is to be used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

The Atlas Spine Spacer is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels(s). This device is to be used with autogenous bone graft. The Atlas Spine Spacer is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

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| Prescription Use ___X____ (Part 21 CFR 801 Subpart D) | AND/OR | Over-The-Counter Use _____ (21 CFR 801 Subpart C) |
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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark A. Milhouse



**(Division Sign-Off)**

*(Posted November 13, 2003)*

**Division of General, Restorative, and Neurological Devices**

**510(k) Number** K081880

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